

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/10/2011 has been entered.

Claims

Claim 3 is canceled.

Claims 1, 2, and 4-8 are pending.

Claims 5 and 7 are withdrawn.

Claims 1, 2, 4, 6, and 8 are under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over translation of JP 2000-344656 to Kurimura et al., as supplied by applicant, in view of USPN 6,193,956 to Liu et al. and USPN 4,303,676 to Balazs.

Applicant Claims

Applicant claims a topical composition comprising a hyaluronate fragment having a molecular weight of 50,000 to 750,000 and retinal.

Applicant further claims fragments having a molecular weight from 50,000-250,000 and 250,000-750,000, and methods of treating skin by application of said compositions.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kurimura et al. teach cosmetic formulations for application to the skin for treating skin roughness, which reads on wrinkled or dry skin (abstract), comprising hyaluronic acid having a molecular weight from 10,000-600,000 (claims and [5]) and retinol acetate and vitamin A oil ([11] and examples), as pertaining to claims 1, 2, 4, 6, and 8.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Kurimura et al. do not teach hyaluronate as claimed in claims 1, 2, and 8. This deficiency in Kurimura et al. is cured by Balazs. Balazs teaches that either hyaluronic acid or sodium hyaluronate may be used as a skin moisturizer (col. 1). It is noted that Liu et al. also teach hyaluronic acid (col. 10, line 25) and hyaluronate (example 28).

Further, Kurimura et al. do not teach retinal as claimed in claim 1. This deficiency is cured by Liu et al. Liu et al. teach topical skin care formulations comprising functionally equivalent retinoids including retinal and retinol acetate (col. 1, line 43 to col. 2, line 10). Functional equivalency of retinal and retinol acetate is also evidenced by US 2002/0114819 to Tashiro et al. [13].

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the use of hyaluronate, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Kurimura et al. with hyaluronate as taught by both Balazs and Liu et al. in order to produce the invention of instant claim, 1, 2, and 8.

One of ordinary skill in the art would have been motivated to do this because all references teach topical skin care formulations, Kurimura et al. teach the use of hyaluronic acid and Balazs and Liu et al. teach that hyaluronic acid and hyaluronate both act to moisturize the skin. Therefore it would have been obvious to utilize the hyaluronate of Balazs and Liu et al., in the formulations of Kurimura et al. in order to use a functionally equivalent moisturizer.

Regarding the use of retinal, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Kurimura et al. with retinal as taught by Balazs in order to produce the invention of instant claim 1.

One of ordinary skill in the art would have been motivated to do this because both references teach topical skin care formulations, Kurimura et al. teach retinol acetate and Liu et al. teach that retinal and retinol acetate are functional equivalents. This fact is also evidenced by Tashiro et al. Therefore it would have been obvious to utilize the retinal of Liu et al., in the formulations of Kurimura et al. in order to use a functional equivalent of retinol acetate.

Regarding claims 4 and 6, all references teach topical application for skin treatment which reads on the method steps of claims 4 and 6.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,193,956 to Liu et al. in view of USPN 4,303,676 to Balazs.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Liu et al. teach topical compositions comprising retinal (col. 3, lines 18-32 and col. 10, lines 23-28), that retinoids are suggested for treating wrinkles and dryness of the skin (col. 1, lines 43-49), said compositions further comprising hyaluronic acid (col. 10, lines 19-28) and that hyaluronic acid provides moisturizing benefits and aids in treating wrinkles (col. 10, lines 23-28 and col. 11, lines 11-14), as pertaining to claims 1, 2, 4, and 6.

***Ascertainment of the Difference between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Liu et al. do not teach molecular weights of said hyaluronic acids as claimed in claims 1 and 2. This deficiency in Liu et al. is cured by Balazs. Balazs teaches moisturizing skin care compositions comprising more than one hyaluronate fraction, one having lower MW at 10,000 to about 200,000 Da and one having a higher MW at 1-4.5 million Da and that lower molecular weight penetrates deeper into the tissue while higher molecular weight will not penetrate as far (col. 1, lines 59-67 and col. 2, line 59 to col. 3, line 2). Balazs also teaches that said lower MW fractions are produced through heat treatment of higher (1,000,000 - 4,500,000 Da) MW fractions and gives time and temperature parameters for said mw reduction (col. 2).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Regarding the limitation of molecular weight, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the

formulations of Liu et al. with more than one hyaluronate fragment having different molecular weights, one between 50,000 and 750,000 and another between 250,000 and 750,000 as taught by Balazs in order to produce the invention of instant claims 1, 2, and 8.

One of ordinary skill in the art would have been motivated to do this because Liu et al. teach hyaluronic acid used in topical skin care compositions used for moisturizing purposes and Balazs teaches hyaluronic acid and hyaluronate used in moisturizing skin care compositions and molecular weight ranges to use as well as the fact that different mw ranges will penetrate to different skin layers. Therefore it would have been obvious to utilize the 1-4.5 million Da hyaluronate molecular weights of Balazs and to modify said fragments into the desired number of different MW fractions, including one between 50,000 and 250,000 and one between 250,000 and 750,000, in order to moisturize the skin at different layers, in the formulations of Liu et al. in order to produce moisturizing compositions using hyaluronate fractions with a known molecular weight ranges to penetrate to different depths in the skin.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 5/10/2011 have been fully considered but they are not persuasive.

Applicant argues that a combination of hyaluronate and retinal result in synergistic results and point to the data found in the Barnes et al. reference which was provided by applicant.

This argument is not found persuasive because the data in Barnes et al. is at most additive and not synergistic. Further, the HA fractions used in Barnes et al. are not commensurate in scope with the claimed molecular weight fractions.

Declaration/Affidavit

The declaration under 37 CFR 1.132 filed 5/10/2011 is insufficient to overcome the rejection of claims 1, 2, 4, 6, and 8 based upon the obviousness rejection as set forth in the last Office action because: The compositions of Barnes et al. are not commensurate in scope with the instant claims. Barnes et al. teaches compositions comprising retinal and hyaluronate fragments having a molecular weight range of 50,000 to 400,000 while the instant claims recite a range from 50,000-750,000, from 50,000 to 250,000, and from 250,000 to 750,000. The declarant attempts to remedy this by providing the logic that "The experiments with hyaluronate fragments of 50,000-750,000 should certainly reveal similar results. However, applicant has provided no data for any of the claimed ranges as claimed.

The Barnes et al. reference's showing is not commensurate in scope with the instant claims in that Barnes et al. discuss experimentation on both mice and humans, however, all of the data is directed to mice only. The instant claims recite "topical compositions" and are not limited to either mice or humans. In order to use said data and an argument to synergy, the claims must be limited to mice, as testing between mice and humans would not be expected to render the same results.

Further, the results pointed to in Barnes et al. are not synergistic. At best said results are additive or a difference in degree. There is no evidence of synergy and applicant has provided no rational for synergy, therefore the obviousness rejection has not been overcome with any showing of unexpected results.

Conclusion

Claims 1, 2, 4, 6, and 8 are rejected.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on monday-friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

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Supervisory Patent Examiner, Art Unit 1616